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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,166	10/23/2003	Ronit Yahalomi	1662/611055	2633
26646	7590	10/17/2006	EXAMINER	
KENYON & KENYON LLP ONE BROADWAY NEW YORK, NY 10004			PUTTLITZ, KARL J	
			ART UNIT	PAPER NUMBER
			1621	

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/693,166

Applicant(s)

YAHALOMI ET AL.

Examiner

Karl J. Puttlitz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 97-102 is/are pending in the application.
- 4a) Of the above claim(s) 100 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 97-99, 101 and 102 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>various</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 97-99, 101 and 102, drawn to a crystalline form of nateglinide classified in class 562 subclass 405+.
- II. Claim 100 drawn to a method of lowering blood sugar in a mammal classified in class 514 subclass 553+.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method of lowering blood sugar can be done with materially different products, e.g., insulin.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Payam Moradian on 5/8/2006 a provisional election was made with traverse to prosecute the invention of Group I claims 97-99, 101 and 102. Affirmation of this election must be made by applicant in replying to this Office action. Claim 100 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Inventorship

In view of the papers filed 1/30/2006, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by adding Schlomit Wizel.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Specification

The examiner notes the presence of non-initialed marks on page 13 of the specification. Applicant is required to advise if the mark is meant to be a change in the text.

Claim Rejections - 35 USC § 112 (Note)

The examiner notes that claims 98 and 102 make reference to features in the figures. In this regard the examiner notes that normally, where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993). The instant case is an exceptional circumstance since the claims are directed to solvated forms of nateglinide crystals, which are characterized in the art by XRPD patterns and FTIR spectra. Moreover, since the claims are read not in a vacuum, but are informed by the specification, and since those of ordinary skill

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describe the instant crystalline forms in the manner claimed, claims 98 and 102 are clear to those skilled in the art.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 97-99, 101 and 102 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 5,463,116 to Sumikawa et al. (Sumikawa).

The rejected claims are drawn to a crystalline form of nateglinide characterized by an XRPD pattern with peaks at 4.7, 7.4, 13.8 and 17.0 +/-0.2 theta, wherein the crystalline form is substantially free of a peak at 3.8 +/-0.2 theta, or an XRPD pattern as

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substantially depicted in a figure selected from the group consisting of FIG. 65, FIG. 66, FIG. 67 and FIG. 68.

The rejected claims also cover a pharmaceutical formulation comprising the crystalline form characterized by the claimed XRPD patterns and a pharmaceutically acceptable excipient.

The rejected claims also cover a crystalline form of nateglinide characterized by an FTIR spectrum with peaks at 3350, 1701, 1646 and 1291 cm^{-1} , or a crystalline form that has an FTIR spectrum as substantially depicted in FIG. 31.

At the onset, the examiner notes that the XRPD patterns, figures and FTIR spectra covered in the rejected claims all conform to the so called "U-type" crystals of nateglinide, or, as depicted in figure 17, for example "U form". In this regard, the specification states that nateglinide forms B, H and U are related in that they may be prepared from a two solvent system. The two solvent system used is a mixture of a solvent and an anti-solvent. Example of suitable antisolvents are C_5 to C_{12} saturated hydrocarbons such as hexane and heptane. Examples of suitable solvents are C_1 to C_5 alcohols such as methanol, ethanol, isopropanol, n-butanol and n-propanol. After crystallization, the crystals are recovered by techniques well known in the art, such as filtration and centrifugation. See pages 16 and 17 of the specification.

In relation to the above, Sumikawa teaches preparation of a batch of B and H nateglinide crystals. Specifically, Sumikawa teaches crystallization from good solvents in which N-(trans-4-isopropylcyclohexylcarbonyl)-D-phenylalanine is more readily soluble such lower alcohols, such as methanol, ethanol and examples of poor solvents

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include hexane., see description bridging columns 4 and 5. The patent also teaches pharmaceutical compositions, see column 6, lines 40-44.

Accordingly, since the crystals prepared in Sumikawa are prepared substantially similar to the U crystals covered by the instant invention those of ordinary skill would expect that at least a portion of the crystals in Sumikawa are of the U-type, and therefore anticipate the crystalline forms covered by the rejected claims. Alternatively, those of ordinary skill would expect that the crystals prepared by Sumikawa would invariably exhibit the XRD patterns and FTIR spectra covered in the rejected claims, and therefore, the U-type crystalline form would be within the motivation of those of ordinary skill, and are thus *prima facie* obvious. See M.P.E.P. § 2112.01 ("Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)."). Therefore, the rejected claims are anticipated by Sumikawa within the meaning of section 102, or alternatively, rendered *prima facie* obvious in view of Sumikawa within the meaning of section 103, since the reference invariably teaches the crystalline forms of nateglinide, or suggest the elements of the claimed crystalline forms with a reasonable expectation of success.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 97-99, 101 and 102 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 97 of copending Application No.

10/622905. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 97-99, 101 and 102 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 27- 29 and 31 of copending Application No. 10/746697. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karl J. Puttlitz whose telephone number is (571) 272-0645. The examiner can normally be reached on Monday to Friday from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at telephone number (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Karl J. Puttlitz
Assistant Examiner